K003822

JAN - 8 2001

510(k) Summary

Proprietary name: ISOLA Closed Dual Rod Connectors

Common Name: Closed Dual Rod Connector

Classification Name and Reference: Spinal interlaminal fixation orthosis, §888.3050
Pedicle screw spinal fixation §888.3070

Proposed Regulatory Class: Class II

Device Product Code: 87/KWP, 87/MNH, 87/MNI

The titanium ISOLA Closed Dual Rod Connectors are designed to interface with various spinal anatomies and accept 4.75mm, 5.5mm and 6.35mm diameter rods. The stainless steel ISOLA Closed Dual Rod Connectors are designed to interface with various spinal anatomies and accept 4.75mm, 5.0mm and 6.35mm diameter rods.

The differences between the connectors that are the subject of this submission and the previously cleared connectors are that the rods pass through a solid band and the rods are secured using set screws

The ISOLA Closed Dual Rod Connectors are manufactured from either implant grade titanium alloy or stainless steel that conform to ASTM standards F-136 and F-138, respectively.

The ISOLA Closed Dual Rod Connectors are substantially equivalent to the AcroMed ISOLA Transverse Rod Dual Connectors cleared in K921090. The set screw locking feature is the same as that used in ISOLA hooks previously cleared in 510(k) K884163. The substantial equivalence is based upon an equivalence in design, materials, manufacturing methods, intended use, and relative indications and contraindications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2001

Mr. Frank Maas
Manager, Regulatory Affairs
DePuy Acromed, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K003822
Trade Name: ISOLA Closed Dual Rod Connectors
Regulatory Class: II
Product Code: KWP, MNH, MNI, KWQ
Dated: December 5, 2000
Received: December 11, 2000

Dear Mr. Maas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K003822

Device Name: ISOLA Closed Dual Rod Connectors

Indications for Use:

The indications for use for the modified devices described in this submission are the same as those for the ISOLA Transverse Rod Connector cleared in 510(k) K921090. The indications are as follows:

The Posterior ISOLA System when used with pedicle screws is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar and sacral spine.

The Posterior ISOLA System when used with pedicle screws is indicated for degenerative spodylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine.

The Posterior ISOLA System is also indicated for pedicle screw fixation for Grade 3 and 4 spondylolisthesis at L5-S1, in skeletally mature patients, utilizing autologous bone graft, having the device fixed or attached to the lumbar or sacral spine and intended to be removed after solid fusion is attained. Levels of attachment for this indication range from L3 to the sacrum.

The Posterior ISOLA Spinal System when not used with pedicle screws is intended for posterior hook, wire, and/or sacral/iliac screw fixation from T1 to the ilium/sacrum. The non-pedicle screw indications are spondylolisthesis, degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis and kyphosis), tumor, fracture and previous failed fusion.

The Anterior ISOLA system is intended for use in correcting scoliotic, lordotic or kyphotic spinal deformities by establishing an axially and rotationally rigid fixation bridge parallel to the long axis of the spine. The system is indicated in situations where loss of correction is expected, where severe scoliosis exists or where pelvic obliquity is present. Spinal levels for anterior ISOLA instrumentation are from T5-L4.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(per 21 CRF 801.109)

OR Over-The-Counter Use_____

(Optional Format 1-2-96)

for Mark N. Milleman

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003822